Message

**From:** Miller, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FA0582F5BA6540C687844F9289A4F74F-DAVID J. MILLER]
**Sent:** 11/4/2019 11:21:11 PM
**To:** Doherty, Michael [Doherty.Michael@epa.gov]
**Subject:** RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

Yes, I recall.

I agree it would be outside JMPR or CCPR responsibilities to make a request. But it may be that this is what Dr. Hodges expects (or hopes) to happen, I don't know. But I agree with you. I think the JMPR/CCPR needs to requests studies like they need a hole in the head. I can't see any advantage to them to volunteering to take on this responsibility. None.

With respect to EPA submitting studies without consent of the data owner, I think – regardless of whether JMPR deciding to use them or not – that this would be problematic (read: not legal) for EPA in and of itself, and I can't see this being done.

David.

**From:** Doherty, Michael <Doherty.Michael@epa.gov>
**Sent:** Monday, November 04, 2019 3:34 PM
**To:** Miller, David <Miller.DavidJ@epa.gov>
**Subject:** RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

I do not think JMPR would be willing to make a request. To do so is, in my opinion, well outside the scope of JMPR and would be seen as a thinly veiled attempt to bypass sponsor responsibilities.

There's still the issue about EPA submitting studies without consent of the data owner. I think this is information that I've already shared: In a brief conversation during the 2018 JMPR regarding an identical situation for another compound, JMPR concluded that it would not be able to use studies that were submitted without said consent.

**From:** Miller, David <Miller.DavidJ@epa.gov>
**Sent:** Monday, November 4, 2019 2:02:30 PM
**To:** Doherty, Michael <Doherty.Michael@epa.gov>
**Subject:** FW: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

Mike-

Do you know if JMPR would be willing to submit a FOIA request to EPA in case Dr. Hodges does not (or cannot)? I suspect JMPR (or CCPR) will not do that. It is also not clear that it would be granted, if indeed JMPR/CCPR did submit it (multinational status etc.). That question is for another day, but any email from Dr. Hodges to the Codex Secretariat that suggests that EPA will supply the data to Codex that leaves out the part that it is encumbent upon Codex to actually *request* the data from EPA is leaving out an important fact.

If JMPR or CCPR is or will not be willing to submit such a request, then it is up to Dr. Hodges to do it. And he has as of yet not, as per the email from Earl below. Despite Dr. Hodges being told (in September?) that he needs to. And despite

him implying in his earlier email to which Codex Secretariat personnel were cc' d that he is asking for any upcoming CCPR meeting covering aldicarb to be delayed "to allow enough time for the US EPA to submit the studies to the CCPR".

David.

**From:** Ingram, Earl <Ingram.Earl@epa.gov>
**Sent:** Monday, November 04, 2019 1:56 PM
**To:** Miller, David <Miller.DavidJ@epa.gov>
**Cc:** Furlow, Calvin <Furlow.Calvin@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Sadowsky, Don <Sadowsky.Don@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>
**Subject:** RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

We have not received a FOIA request from Mr. Hodges.

**From:** Miller, David <Miller.DavidJ@epa.gov>
**Sent:** Monday, November 04, 2019 1:27 PM
**To:** Ingram, Earl <Ingram.Earl@epa.gov>
**Cc:** Furlow, Calvin <Furlow.Calvin@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Sadowsky, Don <Sadowsky.Don@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>
**Subject:** RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

Ok. Thank you.

And can I or can I not assume that ITRMD has such formal FOIA request in hand from Dr. Hodges as per Don S's Item (1) below from September?

David

**From:** Ingram, Earl <Ingram.Earl@epa.gov>
**Sent:** Monday, November 04, 2019 1:14 PM
**To:** Miller, David <Miller.DavidJ@epa.gov>
**Cc:** Furlow, Calvin <Furlow.Calvin@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Sadowsky, Don <Sadowsky.Don@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>
**Subject:** RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

Yes.

**From:** Miller, David <Miller.DavidJ@epa.gov>
**Sent:** Monday, November 04, 2019 12:54 PM
**To:** Ingram, Earl <Ingram.Earl@epa.gov>
**Cc:** Furlow, Calvin <Furlow.Calvin@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Sadowsky, Don <Sadowsky.Don@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>
**Subject:** RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

So…. Was the information below suggested by Don Sadowksy actually conveyed to Dr. Hodges by OPP ITRMD?

David

**From:** Ingram, Earl <Ingram.Earl@epa.gov>
**Sent:** Monday, November 04, 2019 12:38 PM
**To:** Miller, David <Miller.DavidJ@epa.gov>

**Cc:** Furlow, Calvin <Furlow.Calvin@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Sadowsky, Don <Sadowsky.Don@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>
**Subject:** RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

You are welcome.

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**From:** Miller, David <Miller.DavidJ@epa.gov>
**Sent:** Monday, November 04, 2019 11:54 AM
**To:** Ingram, Earl <Ingram.Earl@epa.gov>
**Cc:** Furlow, Calvin <Furlow.Calvin@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Sadowsky, Don <Sadowsky.Don@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>
**Subject:** FW: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

Thanks, Earl. This is helpful.

I see that Don suggests in his September email the following:

**Ex. 5 Attorney Client (AC)**

Was the above information conveyed to Dr. Hodges? If so: (A) it seems EPA is being fairly clear with Dr. Hodges; and (B) Dr. Hodges is not being clear with Codex.

David.

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**From:** Ingram, Earl <Ingram.Earl@epa.gov>
**Sent:** Monday, November 04, 2019 11:31 AM
**To:** Miller, David <Miller.DavidJ@epa.gov>; Furlow, Calvin <Furlow.Calvin@epa.gov>
**Cc:** Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Sadowsky, Don <Sadowsky.Don@epa.gov>
**Subject:** RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

David,

**Ex. 5 Attorney Client (AC)** as we were advised by Don Sadowski in OGC. See Don's September 26 letter.

I have copied Don.

Earl

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**From:** Miller, David <Miller.DavidJ@epa.gov>
**Sent:** Monday, November 04, 2019 11:15 AM
**To:** Furlow, Calvin <Furlow.Calvin@epa.gov>; Ingram, Earl <Ingram.Earl@epa.gov>
**Cc:** Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Johnson, Marion

<Johnson.Marion@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>
**Subject:** RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

Dear Earl and Calvin,

I read the message below from Mr. Larry Hodges which was sent to you as well as a number of officials from the Codex Secretariat and well as the Australian Chair of the CCPR's electronic Working Group on Priorities. Larry's email below -- whether accurate or not -- seems to suggest that US EPA itself will be providing the studies to CCPR, regardless of what I understand are objections to this from Bayer Crop Science. I am not an attorney and not an expert in 6(a)(2) , but it strikes me that EPA's release of this to CCPR would be in violation of the law. If I am wrong in that, I would be happy to be corrected. Have you consulted with OGC on this and have they indicated that EPA's release of this proprietary Bayer data to CCPR is alright? It would be helpful for you to send to me and Aaron Niman any communication you have had with Mr. Hodges indicating that it is US EPA's intention to release proprietary Bayer data to CCPR, data which last I know Bayer had not agreed could be released by the Agency.

With Mr Hodges cc'ing a slew of officials from CCPR with an email that asks the planned upcoming CCPR meeting covering aldicarb to be delayed "to allow enough time for the US EPA to submit the studies to the CCPR", this certainly to me now implies that EPA had agreed to and endorses release of the Bayer data, and puts EPA -- and our US Delegation to CCPR - in a poor light if this data is not later forthcoming. I note that it confuses the CCPR planning and prioritization process and may ultimately displace other legitimate pesticides on the CCPR priority list, thereby potentially delaying their approval.

Mr. Hodges in his email appears to have placed the onus on EPA to provide the Bayer data required by JMPR to Codex. If this is true, it would be useful to hear this from you two directly. If not true, then I believe information that Mr. Hodges provided in his email below needs to be clarified by indicating that EPA has **not** agreed at this time to release the Bayer data to Codex so that any misimpressions can be corrected. What's there now in his Mr. Hodges email certainly gives that impression.

Clarification on this point from the both of you would be appreciated.

Thank you.

Regards,

David.

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David J. Miller CAPT | USPHS
U.S. Delegate to Codex Committee on Pesticide Residues (CCPR)
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

**From:** Larry Hodges <larryhodges@meycorp.com>
**Sent:** Monday, November 04, 2019 9:59 AM
**To:** Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>; MADSEN, Soren <madsens@who.int>
**Cc:** VERGER, Philippe <vergerp@who.int>; Yang, YongZhen (AGPM) <YongZhen.Yang@fao.org>; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Ingram, Earl <IMCEAMAILTO-Ingram+2EEarl+40epa+2Egov@namprd04.prod.outlook.com>; Furlow, Calvin <Furlow.Calvin@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Antoine Puech <antoinepuech@meycorp.com>
**Subject:** RE: Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

Dear Mr. Reichstein and Mr. Madsen,

As previously explained, AgLogic Chemical (the current and only registrant of aldicarb) is committed to supporting the existing aldicarb MRLs but we do not have access to the aldicarb studies. These studies were submitted to the US EPA by Bayer CropScience and it is unlikely that the US EPA will be able to provide the aldicarb studies to the CCPR by December 1, 2019. As it is extremely important that aldicarb not be removed from the CCPR list of pesticides we propose that the aldicarb reevaluation be rescheduled from 2020 to 2021 to allow enough time for the US EPA to submit the studies to the CCPR.

Please respond to this email and let us know how the CCPR wishes to proceed and what we can do to ensure the necessary aldicarb studies are available for review.

Best Regards,
Larry Hodges, Ph.D.
Director of Regulatory Affairs
AgLogic Chemical LLC

Phone: 919-932-5800

**From:** Larry Hodges
**Sent:** Thursday, October 10, 2019 1:08 PM
**To:** Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>; MADSEN, Soren <madsens@who.int>
**Cc:** VERGER, Philippe <vergerp@who.int>; YongZhen.Yang@fao.org; Miller, David <Miller.DavidJ@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Ingram, Earl ; Furlow, Calvin <Furlow.Calvin@epa.gov>; Johnson, Marion <Johnson.Marion@epa.gov>; Antoine Puech <antoinepuech@meycorp.com>
**Subject:** Toxicological and Residue Evaluation Aldicarb (117) by CCPR/JMPR

Dear Mr. Reichstein and Mr. Madsen,

I am sending this email to advise you of the current status of the data submission for aldicarb (117) and to ask for guidance on the path forward. The attached two documents, summarized below, provide the background on our attempt to provide the CCPR with the requested aldicarb studies.

On October 24, 2018 AgLogic Chemical LLC was advised by Mr. Ian Reichstein that aldicarb was reinstated as a supported compound awaiting periodic review and would be placed as a confirmed listing for the 2020 Schedule.

We notified the CCPR that AgLogic is a generic registrant and, as allowed by US law, our aldicarb registration is supported by toxicology and residue data that were developed and submitted to the US Environmental Protection

Agency (EPA) by aldicarb's previous registrant, Bayer CropScience. We are not allowed to have copies of the actual studies that support registration and, therefore, despite our best intentions, we are not able to submit these studies to the JMPR for review.

We suggested that the since the EPA already has the supporting studies, the aldicarb reviews could be written by the EPA's residue and toxicology experts that participate in the JMPR or, alternatively, the EPA could provide the required studies to the JMPR for review by someone not from the EPA.

On May 22, 2019 AgLogic Chemical was notified by Mr. Soren Madsen that the aldicarb studies should be submitted to the JMPR for review in order to avoid possible (or perceived) conflicts of interest. We were told that the JMPR secretariat seeks to assign monographers and reviewers that have not been directly involved in recent national evaluations of the assigned compound.

We immediately contacted the EPA and asked if they could submit the aldicarb studies directly to the JMPR and EPA said that it was most appropriate to work through the Freedom of Information Act (FOIA). That determination was made based upon the requirements set forth under Section 10(g) of FIFRA, which, in part, restricts the availability of how studies/data submitted to the EPA can be released to a specific requestor. At this point the EPA Office of General Counsel contacted Bayer CropScience to get their consent to release the aldicarb studies to the JMPR.

On July 29, 2019 AgLogic Chemical was notified that Bayer decided not to consent to the EPA's direct release of aldicarb toxicology and residue studies to the JMPR. However, the EPA said they would consider if it was possible for them to provide the studies directly to the CCPR without agreement from Bayer.

On September 27, 2019 the EPA stated *"To pursue a definitive decision, CCPR would need to submit a FOIA request, identify the specific studies being requested, and identify all individuals who would have access to the requested studies. EPA would require signed Affirmations of Non-multinational Status from each of those individuals as one of the initial steps after receiving the request. I don't know if EPA would be able to make a final determination on disclosure by December 1, 2019."*

While the studies requested are in the public domain, the only way that the aldicarb studies can be provided to the CCPR is through Freedom of Information requests that are submitted to the EPA by the assigned CCPR reviewers. If this procedure is acceptable Ag Logic Chemical will identify the specific aldicarb studies that should be requested under FOIA. We will include the complete study title and MRID number so that EPA will not have any problem locating the correct studies. We will provide the list of studies to the CCPR so they can submit the FOIA requests.

As it is unlikely that this process can be completed by December 1, 2019, we propose that the aldicarb reevaluation be rescheduled from 2020 to 2021 to allow enough time for the EPA to submit the studies to the CCPR.

Please let us know how the CCPR wishes to proceed and what we can do to ensure the necessary aldicarb studies are available for review.

Best Regards,
Larry Hodges, Ph.D.
Director of Regulatory Affairs
AgLogic Chemical LLC

Phone: 919-932-5800